



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,150	04/27/2001	Pierre Chambon	065691/0219	7311

22428 7590 07/28/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,150

Applicant(s)

CHAMBON, ET AL.

Examiner

Gerald G Leffers Jr., PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-13, 15-24, 26-46 and 49-54 is/are pending in the application.
- 4a) Of the above claim(s) 26-46 and 49-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4 and 15-18 is/are rejected.
- 7) ☒ Claim(s) 3, 5, 6, 8-13, 19-24, 53 and 54 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1636

DETAILED ACTION

Receipt is acknowledged of amendments filed 12/9/2003 and 5/11/04 in which several claims were amended (claims 1, 8, 12-13, 15, 18, 23, 33, 39, 42-43 and 50), claims were cancelled (claims 7 and 14) and in which a new claim was added (claim 54). Claims 1-6, 8-13, 15-24, 26-46 and 49-54 are pending in the instant application, with claims 26-46, 49-52 withdrawn from consideration as being directed to nonelected inventions. Pending claims 1-6, 8-13, 15-24 and 53-54 are under consideration.

Response to Amendment

Any rejection of record in previous office actions not addressed herein is withdrawn.
This action is FINAL.

Claim Objections

Claim 54 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. New claim 54 recites, "An isolated nucleic acid comprising the isolated DNA of claim 1 further flanked by additional SSRTS." As claim 1 is itself drawn to the isolated DNA that is comprised within the larger nucleic acid of claim 54, claim 54 is broader in scope and does not further limit claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wild et al (applicants' submission A6; Gene 1998, Vol. 223, pages 55-66; see the entire document). **This rejection is maintained for reasons of record in the office action mailed 9/9/2003 and repeated below.**

Wild et al teach the retrofitting of pre-existing libraries of transposon insertions with FRT and oriV elements in order to use the retrofitted constructs for generation of large quantities of genomic DNA fragments (e.g. the Abstract). In Figure 7, Wild et al demonstrate the generation of isolated DNAs comprising recombination sequences in the order of Lox-FRT-Lox-FRT where the Lox sequences are in opposite orientation with one another and the FRT sequences are in opposite orientation with one another (e.g. Figure 7A). In this example the Lox sequences flank, at least, the first FRT sequence, and the FRT sequences flank the second Lox sequence as well as genomic sequences.

It appears that the Lox-FRT-Lox cassette present in the pMS10.1 and pms10.2 vectors used to generate the recombinant molecules described in Figure 7 comprise additional sequences between the two Lox sites and the FRT site (e.g. see Figure 3; sequences include, at least, oriV, MCS2 and a BamHI restriction site). Therefore, the limitations of claims 2 & 4 have been met.

Art Unit: 1636

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Response to Arguments

Applicant's arguments filed in the response of 12/9/2003 have been fully considered but they are not persuasive. The response essentially argues: 1) that inherent descriptions must necessarily flow from a disclosure, 2) Wild et al teach a system for excising a DNA fragment using the FLP recombinase, 3) specifically, their system requires two plasmids, each having an FRT site that is inserted randomly into the genome, and 4) Wild's random insertion would not necessarily produce a predictable FRT orientation.

While it is true that inherency must "necessarily flow" from the teachings of the prior art, applicants have presented no convincing evidence or rational for why the nucleic acid represented in Figure 7A of the Wild et al reference does not anticipate applicants' invention. From reading the reference, it is clear that Wild et al considered the structure depicted in Figure 7A, where the FRT and Lox sites are in opposite orientation with respect to one another, to be present in the integration products of their experiments. Further, an assertion that one could not necessarily predict the relevant orientations of the FRT/Lox sites for integrants is not convincing. Given the integration constructs taught by Wild et al, it is reasonable to expect at least 1 in 2 possible insertion events would result in the type of structure shown in the second part of Figure

Art Unit: 1636

7 (see pMS10.1 and pMS10.2 in Figure 3 of Wild et al). Given the orientation in the pMS10.1 and pMS10.2 structures, any integration event relative to a single existing insertion of a FRT element in the substrate nucleic acid would *necessarily* result in both of the insertion events described by Figure 7A.

Conclusion

Claims 1, 2, 4, and 15-18 are rejected. Claims 3, 5-6, 8-13, 19-24 and 53 are objected to as being dependent upon a rejected claim. Claim 54 is objected to as not further limiting claim 1, upon which it depends.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636


GERRY LEFFERS
PRIMARY EXAMINER

ggl